



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,093	03/16/2001	Stephanie K. Clendennen	4257-0025.30	8290

23500 7590 12/11/2002

JAN P. BRUNELLE  
EXELIXIS, INC.  
170 HARBOR WAY  
P.O. BOX 511  
SOUTH SAN FRANCISCO, CA 94083-0511

[REDACTED] EXAMINER

MEHTA, ASHWIN D

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1638

DATE MAILED: 12/11/2002

9  
AD

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Applicant No .	Applicant(s)
	09/811,093 Examiner Ashwin Mehta	CLENDENEN ET AL. Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 13 August 2002.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1,5,7-15,19 and 20 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,5,7-15,19 and 20 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 16 March 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to claims 13 and 15 is withdrawn, in light of the claim amendment or cancellation.
3. The rejections of claims 1-3, 5, and 7-19 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph are withdrawn in light of the claim amendments or cancellations.

*Specification*

4. The disclosure remains objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Applicants traverse the objection in the paper filed 13 August 2002. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that hyperlinks and texts that may be formatted as an active link have been removed (response, paragraph bridging pages 6-7). However, the amended text still forms hyperlinks and/or browser-executable code.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 7-19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitation “the MEL7 coding sequence, as presented in SEQ ID NO: 46, in cantaloupe melon genomic DNA” renders the claim and those dependent thereon indefinite. The specification teaches that SEQ ID NO: 46 is the MEL7 mRNA sequence (page, 11, lines 28-31; page 36, Table 10), not the genomic DNA sequence.

In claim 9: the recitation “wherein the heterologous nucleic acid coding sequence is operably linked to control sequences recognized by a host cell” renders the claim indefinite. The claim is dependent on claim 8, which indicates that the heterologous nucleic acid sequence is already operably linked to the MEL7 promoter, which is a control sequence.

In claim 15: there is improper antecedent basis for the recitation “a MEL7 promoter according to claim 1”. Claim 1 is directed to an isolated nucleic acid molecule.

In claim 19: the claim is indefinite because it depends from cancelled claim 18. The claim has been examined here as if it is dependent on claim 15.

6. Claims 1, 7-15, 19 remain and claims 5 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

Art Unit: 1638

application was filed, had possession of the claimed invention. Applicants traverse the rejection in the paper received 13 August 2002.

Applicants argue that the amendment to claim 1 that incorporates sequence information for the MEL7 gene specifies that the invention is directed to a promoter from a single MEL7 promoter (response, page 8, 2<sup>nd</sup> full paragraph). Applicants' response is found persuasive, as the issue raised in the rejection concerned the written description of the promoter sequences of all MEL7 genes of all types of melon plants.

However, amended claim 1 now encompasses any sequence having fruit-associated promoter activity, wherein the sequence is within 1560 nucleotides upstream of SEQ ID NO: 46 in cantaloupe melon genomic DNA. The specification correlates the function of fruit-associated promoter activity with SEQ ID NO: 42, but not to any fragment thereof. The specification does not describe any other nucleotide sequences that may appear upstream of the MEL7 coding sequence in cantaloupe melon genomic DNA as having fruit-associated promoter activity, or any promoter activity. Further, SEQ ID NO: 46 is the sequence of the MEL7 transcript (page 11, lines 28-31), not the genomic sequence. There is no description in the specification indicating that sequence set forth in SEQ ID NO: 46 is also the corresponding genomic coding sequence.

Furtherstill, the specification, for example on page 25, lines 26-27, indicates that a 1.56 kb MEL7 promoter fragment was subcloned as a translational fusion to a nucleotide sequence encoding S-adenosylmethionine, and that the MEL7 promoter is set forth in SEQ ID NO: 42. The specification describes SEQ ID NO: 42 as having fruit-associated promoter activity, but it does not literally describe nucleotides 156-1708, of the 1735 nucleotide sequence of SEQ ID NO: 42, as having promoter activity.

7. Claims 1, 7-15, 19 remain and claims 5 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the MEL7 promoter set forth in SEQ ID NO: 42, and a method of expressing a heterologous nucleic acid sequence in fruit of a transgenic plant comprising operably linking a heterologous nucleic acid coding sequence to SEQ ID NO: 42, does not reasonably provide enablement for any other isolated nucleic acid molecule comprising any other sequence from within 1560 nucleotides upstream of SEQ ID NO: 46 in cantaloupe melon genomic DNA which has fruit-associated promoter activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicants traverse the rejection in the paper received 13 August 2002, as the rejection appeared in the Office action mailed 08 May 2002 for claims 1-3 and 13-19.

One of the issues raised in this rejection in the Office action mailed 08 May 2002 was that the specification was not enabled for isolated nucleic acid sequences comprising fruit-associated promoters of MEL7 genes other than for the promoter set forth in SEQ ID NO: 42. Applicants argue that the amendment to claim 1 overcomes the rejection (response, page 8, paragraph bridging pages 8-9). As amended claim 1 no longer encompasses MEL7 promoters from all melon plants, this issue has been overcome.

The rejection issued in the Office action mailed 08 May 2002 also concerned the lack of enablement for inducing the MEL7 promoter by decreasing the concentration of ethylene. The claim amendments also overcome this issue.

However, amended claim 1 now encompasses any sequence within 1560 nucleotides upstream of the MEL7 coding sequence, as presented in SEQ ID NO: 46, in the cantaloupe genomic DNA that has fruit-associated promoter activity. Applicants argue that it well known in the art that it is possible to alter the sequence of a promoter by small insertions or deletions, and/or by 5' truncations, and to empirically test the activity of the altered promoter. However, the specification does not provide any guidance as to which fragments of SEQ ID NO: 42, or what sequences within 1560 nucleotides upstream of the MEL7 coding sequence, may retain its fruit-associated promoter activity. No information is provided at all concerning the regions of SEQ ID NO: 42 that are important to its fruit-associated promoter activity. The specification at page 25, lines 26-27, indicates that a 1.56 kb promoter fragment, referred to as SEQ ID NO: 42, was used to make expression constructs. However, SEQ ID NO: 42 consists of 1735 nucleotides, and the specification does not mention that bases 156-1708 in particular have any promoter activity, nor does the specification teach any other fragment of SEQ ID NO: 42 that retains its activity. In the absence of any guidance, one skilled in the art is left to make all possible fragments of all possible sizes and test them for retention of activity, which amounts to undue experimentation. Further, the specification does not provide the MEL7 genomic coding sequence. SEQ ID NO: 46 is the sequence of the MEL7 transcript, not the genomic clone.

Further, newly introduced SEQ ID NO: 46 is the sequence that appears in GenBank Accession No. Z70522 (response, page 7, 5<sup>th</sup> full paragraph; specification, page 11, lines 28-31). However, it is noted that this entry was revised on July 5, 2002, and it appears that this sequence is not the same sequence that appeared in this GenBank entry at the time the instant application was filed. It is therefore not clear if one skilled in the art is to use SEQ ID NO: 46 to make the

Art Unit: 1638

use the claimed invention, or the sequence that appeared in this accession number at the time the application was filed. One skilled in the art could not have used SEQ ID NO: 46 at the time the invention was filed, as it was determined at a later date.

Applicants further argue that polymorphisms that do not affect promoter activity may naturally occur, and that promoters having such minor alterations with respect to the exemplified MEL7 sequence are encompassed by claim 1, which recites a promoter whose sequence is within 1560 nucleotides upstream of the MEL7 coding sequence and is exemplified by the upstream sequence presented as SEQ ID NO: 42 (response, paragraph bridging pages 8-9). However, the claims do not encompass insertions or polymorphisms to any promoter sequence. Further, while Applicants in their arguments claim that SEQ ID NO: 42 is an exemplified sequence that is 1560 nucleotides upstream of the MEL7 coding sequence, it is noted that SEQ ID NO: 42 itself consists of 1735 bases.

### *Summary*

8. Claims 1, 5, 7-15, 19 remains and new claim 20 is free of the prior art for the reasons of record stated in the Office action mailed 08 May 2002 for claims 1-3, 5, and 7-19.

9. Claims 1, 5, 7-15, 19, and 20 are rejected.

10. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1638

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



ASHWIN D. MEHTA, PH.D  
PATENT EXAMINER

December 9, 2002